

**REMARKS**

**I. Claim Status**

Claims 1-10 are currently pending and stand rejected. No claim amendments have been made herein.

**II. Claim Rejections under 35 U.S.C. § 103(a)**

***Rejection over JP 10-195056***

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP 10-195056 to Aono et al. ("Aono"). Office Action at 3. Applicants respectfully traverse this rejection.

Under revised M.P.E.P. § 2143, the Examiner bears the burden of establishing a *prima facie* case of obviousness by showing "that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art."

M.P.E.P. § 2143 (citing *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395-97 (2007)). And the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. M.P.E.P. § 2144.08 (citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). In the present case, a *prima facie* case of obviousness has not been established for at least the reasons outlined below.

The Examiner states that "[t]he indiscriminate selection of 'some' among 'many' is *prima facie* obvious." Office Action at 4 (citing *In re Lemin*, 141 U.S.P.Q. 814 (1964)). Applicants respectfully point out that that quotation originates in *In re Rosicky*, 276 F.2d 656 (CCPA 1960). Unlike *Rosicky*, however, that general statement does not apply to

the present case because the facts are distinguishable. For example, in *Rosicky* the appellant was claiming a subgenus of a genus claimed in the prior art. In particular the claims at issue included a piperidine or pyrrolidine ring, whereas the prior art reference generally disclosed an amine (NR'R"R"). *Rosicky* at 659. Although specific compounds having a piperidine or pyrrolidine were not exemplified in the prior art patent, that patent taught that the amine moiety could, in fact, be a piperidine or pyrrolidine ring. *Id.* Consequently the court found that the absent of any disclosure of a specific compound was of "no moment" because the patent itself taught that a piperidine and/or pyrrolidine ring could be used as the amine moiety. *Id.*

In contrast, in the present case, Aono fails to provide any reason, either explicitly or inherently, for one of skill in the art either to modify the expressly disclosed species in Aono or to choose among the infinite compounds encompassed within the Aono genus to arrive at the presently claimed compounds.

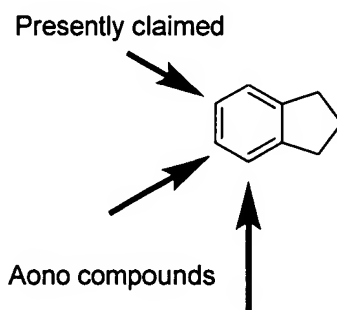
Aono discloses compounds of formula (I) wherein A1 is any 5- or 6-membered hydrocarbon ring, B is any optional substituted heterocyclic group, R is any optionally substituted hydrocarbon ring, and X and Y are each a bond or any divalent group. Accordingly, an infinite number of compounds are encompassed by Aono.

The Examiner must "consider any teachings of a 'typical,' 'preferred,' or 'optimum' species or subgenus within the disclosed genus." M.P.E.P. § 2144.08. That analysis necessarily includes those exemplified compounds that are dissimilar from those presently claimed: "[s]uch a teaching may weigh against selecting the claimed species or subgenus and thus against a determination of obviousness." M.P.E.P. § 2144.08 (citing *Baird* 16 F.3d 380, 382 (Fed. Cir. 1994)).

Here, Aono's disclosed species teach away from the presently claimed compounds because, despite the breadth of Aono's disclosure, the exemplified species are all similar and all of those compounds are dissimilar from the presently claimed compounds.

For example, of the 40 expressly disclosed species in Aono, 39 of those have a direct bond as the X group (Example 1 having OCO as an X group). In contrast, the presently claimed compounds' linking group analogous to Aono's X group is  $-\text{CH}_2-$ .

Furthermore, all of the compounds disclosed in Aono include the  $-\text{Y}-\text{R}$  group at the 4- or 5-position, as shown below. That is in contrast to the substitution of the presently claimed compounds, which are all substituted at the 6-position of the indan ring.



In addition, the exemplary compounds of Aono include for Y a bond, an ether linkage ( $-\text{O}-$  or  $-\text{O}-\text{CH}_2-$ ), or a carbonyl linkage ( $\text{CO}$ ), whereas the presently claimed compounds have in the position analogous a  $-\text{OCOR}$  group.

To establish a *prima facie* case of obviousness, the Examiner must "identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a prima facie obviousness of a new compound claimed." *Takeda Chem. Ind, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). In the present case, the Examiner has not set forth any reason to modify the exemplified

species in Aono. And Aono provides no reason to do so. Rather, as noted above, the specific compounds disclosed in Aono actually teach away from the present compounds of claim 1 and 2. M.P.E.P. § 2144.08 (“teachings of preferred species of a complex nature within a disclosed genus may motivate an artisan of ordinary skill to make similar complex species and thus teach away from making simple species within the genus.”)(citation omitted).

The Examiner also has not provided any reason “to select the claimed species or subgenus from the disclosed prior art genus” in Aono. M.P.E.P. § 2144.08. As noted above, the genus disclosed in Aono comprises an infinite number of compounds. A “[r]ejection of claimed compound in light of prior art genus based on *Petering* is not appropriate where the prior art does not disclose a small recognizable class of compounds with common properties.” *Id.* (citing *In re Ruschig*, 343 F.2d 965, 974, 145 USPQ 274, 282 (CCPA 1965)).

Finally, Applicants note that each element of claims 7 and 9 is not disclosed in Aono. In fact, Aono is wholly silent to the treatment of other disease or conditions besides the treatment of various cancers.

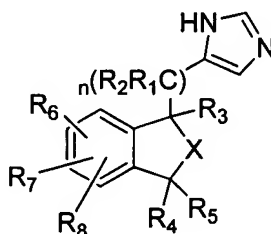
For the foregoing reasons, the rejection over Aono should be withdrawn.

***Rejection over WO 97/12874***

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 97/12874 to Karjalainen et al. (“Karjalainen”). Office Action at 3. Applicants respectfully traverse this rejection.

As mentioned above, the Examiner has the burden of establishing a *prima facie* case of obviousness by, among other requirements, showing that all of the elements of the claims were known in the prior art. M.P.E.P. § 2143. Applicants assert that Karjalainen fails to teach each and every element of the present claims.

In particular, Karjalainen discloses a compound according to the general formula:



wherein each R group is defined as various potential functional groups. p. 1, line 19-p. 2, line 10. Importantly, not one of R<sub>6</sub>, R<sub>7</sub>, or R<sub>8</sub> can be the presently claimed functional group -OCOR, which is presently claimed. See p. 2, lines 2-5. And Karjalainen provides no reason for one of skill in the art to change any one of the groups R<sub>6</sub>, R<sub>7</sub>, or R<sub>8</sub> to be that which is presently claimed. For at least this reason, the Examiner has not established a *prima facie* case of obviousness. Accordingly, the rejection over Karjalainen should be withdrawn.

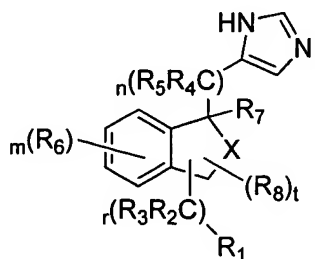
**Rejection over WO 97/12874 in view of WO 01/051472**

Claims 1-10 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Karjalainen in view of WO 01/051472 to Huhtala et al. ("Huhtala"). Office Action at 3. Applicants respectfully traverse this rejection.

As mentioned above, the Examiner has the burden of establishing a *prima facie* case of obviousness. Applicants assert that the Examiner has failed to establish such a case for at least the reasons that applying Huhtala's teachings to Karjalainen would

change a principle function of Karjalainen and that one of skill in the art would have no reason to combine the teachings of Huhtala and Karjalainen.

First, Huhtala teaches a compound according to the general formula:



wherein each R group is defined as various potential functional groups. Huhtala at pp. 2-3. Here again, not one of the substituents  $R_6$  is defined to include the presently claimed -OCOR group. The Examiner states that Huhtala discloses the interchangeability of alcohols and esters. Office Action at 4 (citing Huhtala at p. 8, last full paragraph). Even if that disclosure would provide a reason to one of skill in the art to substitute an  $R_6$  hydroxy group with an ester, the Examiner has ignored the rest of the Huhtala disclosure.

In particular, Huhtala discloses a bulky  $(CR_2R_3)_rR_1$  group which does not overlap with the compounds of Karjalainen. There is no teaching in Huhtala that would suggest to one of skill in the art that removing that group is appropriate. In fact, if one of skill in the art for some reason not disclosed in Huhtala chose to remove that group, its absence would likely change the principle operation of the compounds. See M.P.E.P. § 2143.01. For example, the compounds of Karjalainen (without the bulky  $(CR_2R_3)_rR_1$  group) are disclosed to be general agonists of the alpha2-adrenoceptors, whereas the compounds of Huhtala are generally taught to elicit an antagonistic response at those same receptors: "[The compounds of Huhtala] may also be used for

**reversal** of the effects of alpha2-agonists [(the compounds of Karjalainen)].” Huhtala at pp. 13-14 (emphasis added). Therefore, one of ordinary skill in the art would not have had a reasonable expectation of success in removing that group, as the express teachings of Huhtala indicates that such a removal would likely generate the exact opposite of the desired biological response. And that teaching in Huhtala actually teaches away from Karjalainen. As a result, a *prima facie* case of obviousness cannot be established and the rejection over Karjalainen in view of Huhtala should be withdrawn.

### **CONCLUSION**

In view of the foregoing remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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